V. Community health concerns

ATSDR actively gathers comments and other information from the people who live or work near ORR. ATSDR is particularly interested in hearing from residents of the area, civic leaders, health professionals, and community groups. ATSDR will address these community site-related health concerns in the ORR public health assessments that are related to those concerns.

ATSDR developed a Community Health Concerns Database specifically designed to compile and track community health concerns related to the site. The database allows ATSDR to record, track, and respond appropriately to all community concerns and to document ATSDR's responses to these concerns.

Since 2001, ATSDR compiled more than 2,500 community health concerns from ATSDR/Oak Ridge Reservation Health Effects Subcommittee (ORRHES) comment sheets, written correspondence, phone calls, newspapers, comments made at public meetings (ORRHES and work group meetings), and surveys conducted by other agencies and organizations. These concerns were organized in a consistent and uniform format and imported into the database.

The community health concerns addressed in this public health assessment are those in the ATSDR Community Health Concerns Database related to radioactive iodine from X-10. The following table, derived from the ATSDR database, contains comments and agency responses. In some cases, the responses are similar to those given in other public health assessments.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
Dose reconstruction		
Sources/releases of radionuclides		
1	A community member suggested that some issues do not greatly change outcomes. She believes the most important item on the list is getting all the sources (source terms). A knowledgeable community member said there were probably lots of small releases that weren't identified. Altogether, those small releases could form a substantial amount of iodine.	ATSDR agrees that a complete understanding of the source term is important in the overall assessment. ATSDR is aware that there could have been other sources of radioiodines from the X-10 facility. However, ATSDR and apparently the Oak Ridge Health Effects Steering Panel believe the RaLa process releases were far greater than any other releases of radioiodine from the plant. Considering that the initial review of the reactor operation logs was used to estimate the total production of radioiodines, the Task 1 authors should have had the necessary information to perform the dose reconstruction. For more information on the source terms, please see the Task 1 report (TDOH 1999).
2	A community member asked whether ATSDR and the ORRHES (Oak Ridge Reservation Health Effects Subcommittee) would make a concerted effort to evaluate whether or not major sources of releases of radioiodines from the Oak Ridge Reservation could have been overlooked during Phase I and Phase II of the Oak Ridge Dose Reconstruction (ORDR). The Task 1 ORDR report focused almost entirely on releases of iodine-131(I-131) from the production of radioactive lanthanum (RaLa) from 1944–1956. Other sources of potentially significant releases of radioiodines were from plutonium production beginning in 1944, fuel ruptures at the Graphite Reactor, and from the THOREX process. There may have been sources of I-131 release as well.	
3	What we want is with the outstanding issues we have like source term, uncertainty, confidence interval, central value, adding other sources (like NTS), use of thyroid vs. total body dose; how do these things impact the final assessment?	ATSDR's evaluation of the data from the 1950s would have included any and all sources of radioactive material in the atmosphere regardless of its site of origin. Still, ATSDR believes that soil sampling for the presence of I-129 could supply information to address some of these issues, such as unidentified releases from the X-10 facility.
4	There's one issue that was brought up and it is important—the other ORNL event besides RaLa could expand the time period during which people were impacted. Where RaLa occurred in a certain period of time, evidently thorex or some others were from a different timeframe.	That is correct. Iodine was released after the end of the RaLa process. Please refer to pages 4–20 of the Task 1 report (TDOH 1999).
5	Could the Savannah exposures contribute to exposures in the Oak Ridge area because of Savannah's proximity to Oak Ridge?	Because of the topography and distance between the two plants (over 200 miles point to point), there is little chance that typical releases from the Savannah River Site would impact the Oak Ridge area.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
6	Are the Oak Ridge radionuclide releases much higher or similar to other sources? Are the ORR iodine releases substantially larger than the NTS?	For comparison, the amount of radioactive iodine released from the ORR is about a tenth of that released from Hanford, about 1,500 times less than that released from Chernobyl, and about 2,500 times less than the amounts detected in the United States atmospheric nuclear tests from the Nevada Test Site (NTS).
7	A community member asked what other I-131 releases at the Oak Ridge site were not included in the original I-131 source term.	Iodine production processing was not included in the original source term.
Contaminants selected for further study		
8	Thus far, the only radionuclide for which doses have been reconstructed at several sites and for Nevada Test Site (NTS) releases is I-131. I-131 is the radionuclide that is associated with thyroid cancer, a cancer less often lethal than the cancers that can be caused by the other biologically significant radionuclides released in fallout. There were ranges of other biologically significant radionuclides released from local former AED sites, contained within NTS fallout, and within global fallout. These other radionuclides have not yet been the subject of a detailed dose reconstruction within this country.	CDC was tasked by the Department of Health and Human Services to evaluate this issue. A feasibility study was released in 2003. Briefly, the preliminary findings suggested that the health risks from exposure to fallout from past nuclear weapons tests may be small, but also it would be technically possible to conduct a detailed study of the health impact on Americans of exposure to radioactive fallout from the testing of nuclear weapons in the United States and abroad. The CDC report was peer reviewed by the National Academy of Sciences, which recommended no expanded study of exposure to radionuclides other than I-131. The reasoning was that radiation doses from other radionuclides were much lower than those resulting from the exposure to iodine.
9	Why was X-10 not shown as an arsenic source? It burned coal for a very long period.	During Phase I and Phase II of the Oak Ridge Health Studies, the TDOH conducted extensive reviews and screening analyses of the available information and identified four hazardous substances that may have been responsible for adverse health effects: radionuclides from White Oak Creek, iodine, mercury, and PCBs. In addition to the dose reconstruction studies on these four substances, the TDOH conducted additional screening analyses for releases of uranium, radionuclides, and several other toxic substances. ATSDR scientists conducted a review and a screening analysis of the department's Phase I and Phase II screening-level evaluation of past exposure (1944–1990) to identify contaminants of concern for further evaluation. Based on this review, ATSDR scientists are conducting public health assessments on the X-10 site release of iodine 131, Y-12 mercury releases, ORR PCBs, radionuclides from White Oak Creek, Y-12 uranium releases, K-25 uranium and fluoride releases, and other topics such as the Toxic Substances Control Act (TSCA) incinerator and off-site groundwater.
10	Fluoride and certain other mixed chemicals have the same effects as iodine does. In all of the releases from K-25, fluoride could be a contributing factor.	The release of fluoride and uranium from K-25 will be evaluated in another public health assessment.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
11	Back in the 1950s and 1960s when they were doing a lot of testing, strontium was a big worry. I'd never heard of I-131. Everyone was concerned then about health effects from strontium. Now all this talk about I-131. All of this was from same fallout (I-131 and strontium). Strontium's pathway is basically the same as iodine's.	The deposition pathway from the atmosphere is similar between strontium and iodine, but the critical organs are different: for strontium, bone is the critical organ; for iodine, the thyroid is the critical organ. For a reference individual, the skeleton's mass is about 10 kilograms and that of the thyroid about 30 grams—some 333 times smaller. An equal amount of radioactivity will result in a larger dose to the thyroid than to the skeleton because radiation dose is related to the energy of the radioactive decay and the mass of an organ.
Pathways of exposure		
Groundwater Pathway		
12	Has the porosity of the limestone bedrock below K-25, Y-12, and X-10 been quantified?	ATSDR evaluated the porosity of the bedrock beneath K-25 and X-10 in public health assessment on off-site groundwater releases at the ORR.
Food Consumption Pathway		
13	A Subcommittee member asked if ATSDR was able to get any ecological data from X-10 and other places regarding animal and vegetable consumption by Scarboro residents.	ATSDR's public health assessment for the ORR's Y-12 site evaluates consumption of vegetables grown in Scarboro as the primary pathway of exposure to uranium. For more information, please refer to ATSDR's public health assessment on Y-12 uranium releases, available at http://www.atsdr.cdc.gov/HAC/PHA/oakridgey12/oak_toc.html.
Data and uncertainties in the data		
14	[ATSDR] has been working with DOE management to obtain iodine data. [ATSDR] is working with this air monitoring data that were received from DOE. One critical year, 1954 weekly monitoring data is missing, but DOE is still looking for it. There are also some outstanding questions about how to use the data. These data were from monitors that picked up all particulates, regardless of source, RaLa or wherever. These data could potentially make some of our discussion in obsolete because everything would already be included in the data.	ATSDR was not able to locate the missing 1954 data. On the basis of the other years and comparing the activity in the monitoring and the dates of the atmospheric nuclear tests, ATSDR believes that the monitoring data include the impacts of the nuclear tests. If the recommended soil sampling is performed, then ATSDR will not be ruling out the NTS as any I-129 detected in and around the monitoring locations or any other areas sampled will contain NTS iodine.
15	Do the recently found air monitoring data include fallout from the Nevada Test Site (NTS)?	Yes. Because the historical CAM data non-selectively included the radioactivity in air, the radioactivity detected on the CAM would include any materials injected into the air from the test site and transported across the country.
16	How and where were the new air monitoring data obtained?	The air monitoring data were obtained by a contracting firm in the Knoxville area and supplied to ATSDR.
17	Will the NTS, I-131, and I-133 exposures be included in the analysis?	ATSDR believes that the CAM data from the 1950s include the NTS fallout.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
18	Will the new air monitoring data on I-131 have any effect on adding doses?	ATSDR believes that the CAM data from the 1950s include releases from X-10 and the NTS. Any future dose assessment would, therefore, represent the estimated total dose from both sites.
19	If the new monitoring data already include the fallout component from NTS, care must be taken not to add the component from NTS into the thyroid dose twice.	ATSDR agrees. This is an important public health message that ATSDR needs to impart to the community.
20	One reason [a local scientist] thought it would be important to go back and look at the other releases was they were small and of shorter timeframe and much lower releases. RaLa was over an extended period of time. Others are important if you're going to look at probability of causation. For that end, every little bit counts.	Although the RaLa process occurred over several years, the data in the Task 1 report indicate that the releases did not occur continuously during that time frame. This is important to point out because I-131 has such a short half-life. ATSDR will not be evaluating any of the smaller releases for the purposes of probability of causation, as that is used exclusively for adjudication of legal issues.
Estimated radiation doses and cancer risk		
Dose (general)		
21	How does knowing your dose help you interact with the health system?	Once a dose range can be determined, then the health effects observed in that dose range can be determined. This can be passed on to the medical community so that proper monitoring can be conducted and proper treatment prescribed.
22	How do you think a reconstructed dose would compare with a dose derived from film badge data? Even better for me would be a peer-reviewed publication that validates the models you are using. The issue of trust was a major concern to some ORRHES and community members, and people who do not trust DOE may not trust the results of a DOE-funded report on dose reconstruction (or the results from NIS, state government, or ATSDR for that matter, including this subcommittee). It would certainly be easier for me to argue in favor of using information on reconstructed doses if some parts of the methods and results have been published in a peer-reviewed journal.	ATSDR believes that comparing a reconstructed dose related to releases of I-131 to a film badge will not result in a comparable dose for several reasons. For example, film badges typically are used to evaluate external exposure, which is converted to a whole-body dose. The film badge can be modified to respond to specific energies and types of radiation. Film badge efficiencies have increased over time and older film badges begin to fade; this increases the difficulty of determining older exposures and doses. Many results of other dose reconstruction projects in the United States and other areas of the world have been submitted and published in peer-reviewed journals. Peer review also took place during the grant/contract proposals before the efforts began. The National Academy of Sciences also has reviewed many, if not most, of the dose reconstruction projects in the United States. Their opinions are publicly available at www.nas.edu. ATSDR had the TDOH Task 1 report on the X-10 iodine 131 dose reconstruction technically reviewed by independent experts to evaluate the quality and completeness of the dose reconstruction and to determine if the dose reconstruction provides a foundation on which to base follow-up public health actions or studies.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
23	Individual-specific estimates of the probability of developing thyroid cancer from exposure to fallout from the Nevada testing program are uncertain to a greater degree than the dose estimates because of the additional uncertainty, in particular about the cancer-causing effect of low doses of I-131.	ATSDR agrees. As with any large retrospective dose reconstruction study, there is much uncertainty in the NTS estimates. These uncertainties contributed to the findings of the Institute of Medicine, which stated that doses at the county level have too much uncertainty to serve as a basis for estimates of individual doses.
24	Should the county specific estimates of I-131 released during above ground weapons testing at the NTS be used to determine the thyroid doses from the I-131 to individuals living in that county? Won't excluding the NTS data understate the radiation dose to the public?	According to the Institute of Medicine, doses at the county level have too much uncertainty to be used in an estimate of individual doses. However, peer reports show that soil sampling for I-129 may be useful as an indicator for I-131 distributions. ATSDR believes the NTS releases would have been collected by the air monitoring system. Thus, included in the dose estimates.
25	As you walk across the county line, your dose changes quite a bit.	This is an important fact to realize, especially since the dose reconstruction reports were based on modeled information and not on environmental sampling or monitoring results. Environmental samples, where available, are preferred over modeled values.
26	A Subcommittee member asked [a CDC scientist] about the significance of the dose.	CDC said that the dose number itself is not important. From NTS, this dose ranged from 0 to 200 millirems—a very large range. What are more important are the factors of exposure: How old were you and where were you at the time of exposure? What is your sex? Did you drink backyard milk? Unless you are going to assess the probability of causation, exact dose is not so important.
27	It's mainly young people, so they're going to grow up and they're not the ones who get that second blast. But there will be a new generation there who did get it. All I'm asking is put together a table to show me, and show me the years, and show me the relative doses or something.	ATSDR refers the reader to Table 11.3 and 11.4 on page 11-8 and 11-9 of the 1999 Task 1 report entitled (TDOH 1999). The tables give the estimated thyroid doses to consumers of commercial produce and milk at specified times.
28	How did they/are we looking at the X-10's major processes that may still be delivering an effect? There were cesium releases from the dam in 1985 and a flood in 1964 along with regular releases.	The dose reconstruction focused on historical exposures. In this public health assessment, the dose reconstruction's historical data will be combined with the data collected in the past 20 years.
29	I would be more interested in seeing copies of publications in peer-reviewed journals (by you or your staff) that explain the mathematical and statistical details of ATSDR methods for estimating a person's thyroid doses from I-131.	ATSDR estimated the radiological dose to the thyroid using accepted methodology of the ICRP. The dose coefficients published by ICRP contain inherent uncertainties that are outlined in its methodologies.
30	One commenter stated that although there is uncertainty with the dose estimates, there is an even greater degree of uncertainty when you translate those dose estimates to risk estimates.	Yes, that is true.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
Dose and organ-specific estimates		
31	The conversion of organ doses to effective doses is a questionable practice for a public health assessment. It is of interest to note that the use of effective dose for communicating risks to the public for exposure to I-131 was severely criticized by stakeholders at Hanford. The objection to the use of effective dose is that the organ dose has been partially weighted by ICRP for disease severity, years of life lost, and differences between morbidity and mortality for an individual exposed at an average age. Large differences in the ratio between disease incidence and mortality are given a maximum weight of only a factor of 2.	ATSDR agrees with this comment. During the startup of the ATSDR public health assessment, the initial thoughts were to determine the dose to the thyroid, then convert that to a whole body dose; at the time, ATSDR guidance was to evaluate effects on the entire body. Since then, the agency has adopted a more organ-specific dose assessment policy, especially when there are sufficient scientific data (such as in the case of the thyroid and radioiodine exposure) to justify the organ approach.
32	A community member asked if the GAO used the term cumulative effective dose. The community member explained that there was epidemiological evidence of radiological effects in utero down into 1,000 mrem for effective dose. For 5,000 mrem, the organ dose would be used. For example, a child's thyroid would receive 100,000 mrem, which was well into the range of epidemiologically significant effects for both cancer and noncancer. The community member continued that there were several single organs for which an effective dose of 5,000 mrem would be an organ dose of 100,000 mrem, and for some organs, it could be as high as 500,000 mrem. The community member was present at the PHAWG meeting to raise the issue that the use of effective dose was a poor surrogate to risk assessment. He added that if the numbers that ATSDR were proposing were to be organ doses, then he would not have a problem. However, he stated that he has a professional issue with the use of the effective dose for retrospective analysis.	ATSDR understands the community member's concerns. ATSDR lists the effective dose, but also lists the organ dose for the critical organs as proposed by the ICRP.
Dose and whole-body estimates		
33	A community member asked why the I-131 thyroid doses would be converted to whole-body doses.	ATSDR uses minimal risk levels as an estimate of daily human exposure that is unlikely to result in noncancer effects. The agency also evaluates organ-specific exposures and radiological doses, using the weight of evidence approach to compare these doses to levels associated with effects as reported in the toxicological literature.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
Dose and worst case assumptions		
34	The public will interpret that differently. If we use the worst-case approach, we may indeed be laying foundations for lawsuits.	The use of worst-case approaches in health assessments is typical for initial screening evaluations. This approach gives an upper limit to the impacts that a contaminant might have. The central value, assuming the data are robust, can be used as a "normal" exposure scenario. In 1995, the National Academy of Science also stated that screening values are an initial method of uncertainty analysis that can be used to evaluate the need for additional studies.
Dose and sensitive populations		
35	A Subcommittee member added that workers were not the most sensitive population to radioactive iodine—children residing in the affected area outside the gates were the most sensitive population.	That is correct. Children appear to be more sensitive to iodine exposure than individuals over the age of 19.
Combining doses		
36	A Subcommittee member understood that the Idaho Health Effects Subcommittee was the only one that had asked to have the combined doses evaluated.	The Subcommittees in Idaho and at Savannah River Site have been assured that when the I-131 doses are reached in their project, fallout doses will be considered.
37	If you're trying to do a PHA and give people a reasonable idea of what their health risks are, if there's I-131 both from ORR and NTS, it's in this area and affecting the public health. If you ignore the NTS part of it, you won't get accurate health assessment unless our data is so uncertain and we're so conservative on our conclusions that it covers it anyway. Before I would want to approve not adding NTS data in, I'd want to know if would have any affect in the end.	Because the uncertainty in the Task 1 Report is relatively large, and because the uncertainty in the on-line dose is large, the effect of adding doses may not be significant. A recent estimation indicated that the maximum and minimum dose varied by a factor of 3 or more, depending on the county in Tennessee, date of birth, and milk ingestion rate.
38	The basic question is do we add sources. Iodine-131 from ORNL/Oak Ridge has to be in the assessment—no question about that. But then you look at the NTS and iodine; if you carry that logic to the extreme, you also must include Chernobyl, and on and on. You could add at least a dozen sources of I-131, many of them so small that they're not going to impact at all. Follow on: if we accept that we add other sources to Oak Ridge sources, then what about lead, gasoline from automobiles, fallout from TVA because they emit uranium and thorium, etc.?	Doses from radiological exposures can be added; however, if the quality of the individual data sources is not comparable, then the results would be highly questionable. For example, if one set is based on environmental samples while another is based solely on modeled results, then there may be no strong correlation between the data sets. This public health assessment does not address impacts of non-radiological chemical releases; however, there have been efforts to determine the best methodology to combine both chemical and radiological doses, but with no consensus. ATSDR does not support the effort to combine the doses from dissimilar exposures.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
39	We must combine these exposures to NTS atomic tests, with exposures to local site I-131 and I-131 contained in global fallout. These combined exposure doses must then be translated into health risk.	Combining doses might be possible if the data were less uncertain. As pointed out by the Institute of Medicine, the uncertainty is quite large. If the doses are combined, then ATSDR would evaluate the exposure and doses based on tolerable and observable health effects, not on perceived risk numbers. In an attempt to reduce the uncertainty in the potentially impacted areas, ATSDR evaluated the air monitoring data from the 1950s, which includes any and all sources of radioactive materials in the atmosphere regardless of its site of origin. Also, ATSDR is recommending soil sampling for I-129 to address some of these issues, such as unidentified releases from the X-10 facility and releases from the NTS to determine the areas impacted by I-131 releases.
40	The question is should we combine doses? I think when we look at this, even though we look at iodine, we need to look at some of the generic logic that we're talking about and where we're going with this. Are we vs. should we combine doses What does that do to our program or charter?	
41	Since one can add the doses and combine the uncertainties, anything this committee puts out has got to combine the NTS and the Oak Ridge data. If we do not do this, we will run a terrible risk of discrediting ourselves. Also, we should be dealing with central values when we have distributions of values.	
42	A Subcommittee member summarized that the NTS data has tremendous variability, more so than the data for ORR. When there is a lot of uncertainty involved it does not provide a clear picture for members of the public. However, for the purposes of full disclosure, he noted that it seems the general consensus is to use the NTS data, but provide a clear discussion of the uncertainty involved.	
43	A Subcommittee member suggested that the recommendation focus on the impact of the Oak Ridge Reservation itself rather than complicating the issues with added doses from the NTS or other DOE sites, which may also have had impacts.	
44	A community member commented regarding the combining of doses from radioiodine from Oak Ridge and from the Nevada Test Site, it may be impossible to produce risk estimates from the doses. His opinion is that if risk estimates cannot be produced, time should not be spent producing the dose estimates because people do not know how to interpret dose estimates, but risk estimates are meaningful. His recommendation consisted of eliminating the addition of I-131 doses from Oak Ridge and the Nevada Test Site if the risks cannot be estimated.	

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
Dose calculator		
45	A Subcommittee member recommends not adding the doses but having a dose calculator. She interprets the National Academy of Sciences (NAS) report as meaning that there are things more important than adding doses. Namely, these more important things are risk factors. Even [a local scientist] didn't recommend adding doses. He recommended adding probability of causation. [CDC] didn't say that we had to add the doses. At a later point, additional data will be coming in on global exposure. If new data becomes available, will we have to go back in and update our results to account for the new data? Let's just stick to the Oak Ridge data.	A dose calculator is available. It can be accessed at the Web site of the National Cancer Institute: http://cancer.gov/i131 and http://ntsi131.nci.nih.gov/. ATSDR recommends its use for community members if they have specific symptoms associated with thyroid disease and do not know that they were exposed to I-131. The resource can tell them that they may have been exposed to I-131 and that they should see a doctor.
46	PHAWG recommends that ORRHES recommend that CDC/ATSDR establish an online dose calculator so that individuals may obtain estimates of their thyroid doses due to releases of I-131 from the Oak Ridge Department of Energy Reservation and from the Nevada Test Site, along with an option for adding the doses. CDC/ATSDR should provide information to the public on interpretation of the results from the dose calculator and any follow-up action the individual should take as a result of the estimate. Once you've done the work to make the calculator. I'm not sure that calculator is available.	ATSDR agrees. This is important as it pertains to the public health message that ATSDR needs to communicate to the community. ATSDR is not planning to develop an online calculator for the Oak Ridge releases.
47	A Subcommittee member clarified that the calculator can be used in situations where a person already knows he/she was exposed to I-131. She said that a particular community member is suggesting a resource for people to use if they have X, Y, and Z symptoms and they do not know that they were exposed to I-131. The resource can tell them that they may have been exposed to I-131 and that they should go see a doctor.	ATSDR agrees with this comment, especially in the light of the Institute of Medicine report stating that the doses at the county level are too uncertain to estimate individual doses.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
Boron		
48	A commenter asked if boron was used as part of the iodine dose reconstruction process.	Boron was not used as a surrogate to look at iodine. Any boron that may have been detected at the site occurs naturally in the background soils.
49	This boron, is that for the iodine levels that were released during that time period?	
Uncertainty analysis		
50	What is uncertainty analysis? What are the weaknesses (distortions) inherent in using central values? Upper 95th percentile? What are the strengths in each?	Uncertainty analysis is a process generally used in model validations and risk assessments, not health assessments. The uncertainty is defined as the subjective distribution (not the frequency distribution) of an unknown value, generally a representation of the subjective estimate of the probability of a value occurring as seen by the individual. These estimates are subjective because the confidence intervals are chosen on the basis of expert opinions, not on data. For example, natural variability exists in the data. It is therefore very important to distinguish between natural variability and uncertainty due to lack of knowledge. If one cannot separate out the contributions from natural variability and unknown values, then it is important to use the upper 95th percentile of a distribution to draw conclusions.
51	Just because you can rub two numbers together, should you? What about the dose and the uncertainty associated with it? When you rub these two numbers together and combine them, and there is so much uncertainty, how important is the uncertainty? When you go from dose to risk, the uncertainty skyrockets.	ATSDR agrees in principle with the comment. As stated in the previous comment, uncertainty analysis is very important to the concept of model validation. At issue, however, is the concept of error propagation: that is, the uncertainty in the individual parameters is carried through the complete calculations. When the final uncertainty of the calculated value is determined to be essentially equal to or exceeds the nominal value (the result), then the usefulness of the nominal value comes into question.
Cancer risk estimates		
52	Should ATSDR public health assessment focus on dose estimates or risk estimates of I-131? Estimates of lifetime excess cases of thyroid cancer are more appropriate from a public health perspective. A public health response can be developed around dose and estimates of excess cases of cancer.	ATSDR is mandated by Congress to focus on dose. Public health assessments include a preliminary assessment of the risk, but the final assessment is dose-based.
53	Do the risk estimates include benign and malignant thyroid lesions? If benign lesions are included, then the risk estimates are overestimated. Applying the linear threshold model should preclude consideration of benign lesions, because benign lesions are consistent with a nonlinear mode of action and a threshold model.	Typically EPA risk estimates include benign and malignant lesions since risk is determined for morbidity and mortality. ATSDR agrees with the statement that including benign lesions is overconservative, as about 30% of the population has benign thyroid nodules.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
54	Since the past diagnosis of thyroid cancers may be underestimated, and cancer registries are of little help, is there enough present knowledge to extrapolate to what might have occurred in the past?	ATSDR does not believe there is sufficient information for extrapolation to the past, especially since we believe there were problems with the model used to estimate the iodine exposure, distribution, and uptake as related to environmental factors.
55	Although the formula probability of causation PC=R/(B+R) seems simple enough, it is (or should be) based on complicated life-table calculation. As you know, the calculation of R is based on models of the age-specific excess relative risk, which in turn, depend on a radiation dose-response model in which dose may change with time and/or age at risk. The baseline risk also seems to be problematic in the case of I-131 and thyroid cancer. My concern is that other Subcommittee members have not had the background at this point to understand these issues since there has not been a discussion of even the most basic concepts from epidemiology.	Because of this perceived lack of basic epidemiological knowledge, ATSDR provided an overview of the science of epidemiology and helped ORRHES members evaluate the Mangano paper. Copies of the presentations are available at http://www.atsdr.cdc.gov/HAC/oakridge/presentations/index.html.
Task 1 evaluation process		
56	Does Task I estimate the total impact of off-site exposures to the public (both local and non-local) affecting the health of the thyroid gland? If the impacts are under-or-over estimated, estimate by how much.	The Task 1 Report evaluates the impacts of the iodine releases to residents at a distance of about 24 miles from the release point. Based on the modeled information, ATSDR does not believe it is possible to estimate the "over-or-under" estimates because the data are lacking. The modeled information is not detailed enough for ATSDR to determine whether its impact estimates are high or low.
57	There is no mention of the information from Appendix 11-C of the Task 1 Report (i.e., levels of probability of causation of current thyroid cancers due to past exposures to RaLa I-131) in reports from the State of Tennessee. Why was this material not included?	Probability of causation was developed for adjudication of legal claims under the Energy Employees Occupational Illness Compensation Program Act of 2000. An Executive Order from the President ordered the Department of Health and Human Services to develop guidelines (Probability of Causation) to be used by the Department of Labor to assess the likelihood that an employee with cancer developed that cancer as a result of exposure to radiation in performing his or her duties at a DOE facility or Atomic Weapons Employer ("AWE") facility. ATSDR does not consider Probability of Causation suitable for public health assessment activities.
58	I have taken an initial quick look at this report and see no explanation or justification for Equations 2.1 and 2.2. Can you identify references in the peer-reviewed literature that explain why these equations are appropriate, how the lifetime absolute risk factors are estimated, and how these equations would be useful in describing the potential adverse health effects to any specific group of individuals that may have been exposed to releases of iodine-131 from the ORR?	ATSDR recommends that you contact the original authors to have them address this question.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
Health effects/disease		
Thyroid disease non-cancer		
Non-cancer (general)		
59	To what extent could the thyroids of workers and residents have been adversely affected by exposure to contaminants in addition to iodine-131 from the RaLa process? Discuss the cumulative impacts from other radionuclides from RaLa; other radionuclides from other processes at X-10; other thyroid-impacting contaminants released from X-10, Y-12, and K-25; and non-local exposure.	The thyroid gland is the critical organ for exposure to radioactive iodine. For this reason, radioactive iodine—or any of the radioactive materials released—would have the greatest impact on the thyroid gland of workers and residents. Releases of gamma radiation during the RaLa process may have also impacted workers. In addition to radioactive material, endocrine disruption might affect the thyroid. These thyroid dysfunctions may be caused by organohalogens such as PCBs, pesticides, and other compounds. ATSDR has an extensive list of toxicological profiles on its Web site: http://www.atsdr.cdc.gov/toxpro2.html.
60	A community member commented that she has lived in Oak Ridge since birth, her mother was the first woman to work at Y-12 and worked with the calutrons, many family members came to work in Oak Ridge over the years. Now, many family members have developed thyroid problems, nodules, cysts, and Hashimoto's disease. She said that no one in previous generations of her family had thyroid problems. Has there been any research or documentation on thyroid diseases in second generation Oak Ridgers who worked at the plants or whose parents worked at the plants?	ATSDR brought a thyroid disease expert to the Oak Ridge area to inform the medical community about the issues associated with thyroid disease. The expert responded that he saw a study of thyroid cancer incidence in Oak Ridge showing that only children exposed at an age of less than 1 year who had high exposure from drinking local goat's or cow's milk were significantly vulnerable to thyroid cancer or nodules. Nodules occur more frequently with radiation exposure; 5 to 10 nodules are very common in the population even without radiation exposure. Autoimmune thyroid disorders such as Hashimoto disease are familial, but the genetic mechanism has not been discovered. It could come from either side of the family.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
61	A community member noted that there are various thyroid disorders in the community. She thinks the public would want to know any effects I-131 has on any other symptoms, not just malignant tumors, since any damage to the thyroid has the potential to affect other body parts.	ORRHES requested that ATSDR conduct an assessment of health outcome data (cancer incidence) in the eight counties surrounding the ORR. Therefore, ATSDR conducted an assessment of cancer incidence using data already collected by the Tennessee Cancer Registry. This assessment is a descriptive epidemiologic analysis that provides a general picture of the occurrence of cancer in each of the eight counties. The purpose of this evaluation was to provide citizens living in the ORR area with information regarding cancer rates in their county compared to the state of Tennessee. The evaluation only examines cancer rates at the population level—not at the individual level. It is not designed to evaluate specific associations between adverse health outcomes and documented human exposures, and it does not—and cannot—establish cause and effect. The results of the assessment of cancer incidence, released in 2006, indicated both higher and lower rates of certain cancers in some of the counties examined when compared to cancer incidence rates for the state of Tennessee. Most of the cancers in the eight-county area occurred at expected levels, and no consistent pattern of cancer occurrence was identified. The reasons for the increases and decreases of certain cancers are unknown. ATSDR's ORR Assessment of Cancer Incidence is available online at http://www.atsdr.cdc.gov/HAC/oakridge/phact/cancer_oakridge/index.html.
62	A community member's health problems consist of an enlarged thyroid and autoimmune disease. The condition began when handling uranium samples for school and civic demonstrations.	Typically, the kidneys, and not the thyroid, are most sensitive to the effects of uranium (i.e., the critical organ for uranium exposure is the kidney, not the thyroid). Even so, ATSDR believes that the amount of uranium most likely used in these demonstrations was not sufficient to cause any adverse health effects.
63	A Subcommittee member noted the role of endocrine disruption within the thyroid. The community member further explained that if the feedback mechanisms for the thyroid hormone are disrupted, the level of thyroid stimulating hormone (TSH) could be controlled. If you have a situation in which thyroid hormone levels are constantly low then your TSH level will be constantly high, which overstimulates the thyroid and causes cell proliferation. If you control the feedback mechanism then you can control the proliferation that is induced by the TSH. This control mechanism can be set up in the thyroid or in the liver. If you have increased metabolism of thyroid hormones in the liver your thyroid hormone levels can be lowered, which will increase TSH production and cause the cells to keep reproducing within the thyroid. Therefore, there are two different modes of action and using only one model to account for those modes of action overestimates the risk.	ATSDR believes that this is not precisely correct. TSH does not induce proliferation of cells in the thyroid. Rather, its mode of action is to bind to cells within the gland and stimulate those cells to produce and release thyroid hormone, also called thyroxine.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
64	A Subcommittee member mentioned that there are other contaminants in the environment that are endocrine disruptors, such as pesticides. Also, low iodine diets in children are believed to exacerbate the effects of I-131 on the thyroid, causing high cases of malignant thyroid cancer in children.	ATSDR agrees. As previously noted, there are a number of nonradioactive materials in the environment that can impact thyroid function. In addition, iodine-deficient diets, as shown in residents around Chernobyl, can result in adverse thyroid health effects.
Hypothyroidism		
65	A Subcommittee member asked [the thyroid expert] about the frequency of hypothyroidism in the general population.	Hypothyroidism is common, as it is found in 5% of the general population and subclinically in 10% of the older population. If TSH is mildly elevated and the thyroid is normal, most doctors will treat the patient. If TSH is only mildly elevated (5%–10%) and the patient has no complaints, there is a tendency just to observe. If TSH exceeds 12 milli-international units per liter in adults**,** the disease will progress. The international unit is an arbitrary amount of a substance agreed upon by scientists and doctors.
Hashimoto disease		
66	A community member stated that recently she was diagnosed with Hashimoto's disease and asked for a brief summary of this disease.	Hashimoto disease is a chronic autoimmune inflammation of the thyroid that is common in the population and occurs more frequently with age.
Children and iodine deficiency		
67	A Subcommittee member commented, going back to the children of Chernobyl, he had heard that general areas had been iodine deficient, what role would uptake of iodine have played, especially with in utero exposure?	The expert replied that iodine deficiency would have an effect. The fetal thyroid is very active and it would take up whatever iodine—including radioactive iodine—it could get from the mother. The fractional uptake is higher with iodine deficiency, and iodine deficiency would contribute to taking up more of this radioactive iodine that can cause thyroid cancer.
68	A Subcommittee member wanted to know what would have been the iodine intake forty to fifty years ago.	Iodine deficiency is more common in children of mountainous regions or the Midwest. In fact, 25%–30% of the children in the Midwest have goiter. Children around the ocean were less affected because they got plenty of iodine. Due to concerns about iron deficiency in children, a world-wide program was developed to eliminate iodine deficiency by providing iodized salt.
69	Do children pick up more radioactive iodine because of their iodine deficiency?	Yes. Children pick up more radioactive iodine due to their iodine deficiency.
70	A Subcommittee member asked if kids were deficient in iodine in Chernobyl and how their diets compare with those of U.S. children.	Children in Chernobyl probably have diets low in iodine, with intakes of 50 micrograms per day. As a result of the iodine deficiencies, there is a 20% incidence of adolescent thyroid disease in Chernobyl On the other hand, diets of United States children contain 150–200 micrograms of iodine per day; 150 is considered deficient, 50–100 is borderline. Iodine is also ingested from milk, as well as from fortified bread. Although iodine intake overall has fallen 50% in the last 20 years, the U.S. intake is still considered good.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
71	A community member stated that all of her tests had been normal until her family doctor ran an ultrasound, which found all sorts of problems, and since that time she has run into many people in the Oak Ridge area who experience the same situation. Tests are normal until they insist on additional testing, and probably half of them have cancer. The community member stated that she personally knows 37 people who went through 3 to 4 years of having something wrong, which was undiagnosed because their thyroid tests kept coming back normal, and then when further tests were done, such as ultrasound and biopsies, they had major thyroid problems.	The vast majority of patients—nearly all—have normal thyroid function. That is to say that cancer usually occupies a small part of the thyroid, and the rest of the thyroid functions normally, yet cancer can still be present. So a thyroid nodule can contain cancer, but thyroid gland function is normal. This is probably true in more than 95% to 98% of thyroid cancer cases. Nodules are very common: one half to two thirds of adults have thyroid nodules. Probably 95% of these nodules are benign and not cancerous.
Thyroid disease: cancer		
72	Why are females and children (under the age of 5) more susceptible to thyroid cancer and is that true for all cancers?	According to the National Cancer Institute, no one knows the exact causes of thyroid cancer. Doctors can seldom explain why one person gets this disease and another does not. Most people who have known risk factors for thyroid cancer do not get thyroid cancer. On the other hand, many who do get the disease have none of these risk factors.
73	A Subcommittee member asked if people exposed to fallout should be screened for thyroid cancer.	Any nodules in exposed individuals should be biopsied. Nodules in young people, adolescents, are particularly suspicious.
74	So thyroid cancer occurs about four years after exposure?	Thyroid cancer can appear as soon as 4 years after exposure, or earlier depending on the thyroid dose, as was seen in cases of people who received high thyroid doses following Chernobyl.
75	A Subcommittee member asked if thyroid cancer cells are confined to the thyroid.	Thyroid cancer cells are initially confined to the thyroid, but can eventually spread into the bloodstream.
76	In regards to thyroid incidentaloma (occult Thyroid Cancer), a Subcommittee member asked whether the small microcarcinomas progress.	The progression of thyroid incidentaloma, as measured by ultrasound and fine needle biopsy, was 12% in a retrospective study (http://www.medscape.com/viewarticle/466575).

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
77	A community member emphasized that cancer is not the only outcome from radiation exposure. The iodine-131 work is almost entirely focused on cancer as the only endpoint, but cancer is not the only health concern that people have in Oak Ridge. She suggested that ATSDR solicit community people by advertising. Many people in the community are not aware that the issues are being discussed She was particularly concerned about chemicals and the interactive effects with radiation. The toxicological literature includes information on work with synergistic effects that should be coming to the subcommittee. These data gaps are critical data.	Currently, cancers are the only diseases clearly shown to be related to radiation exposure; however, new evidence emerging indicates there are diseases other than cancers that are associated with radiation exposure in atomic bomb survivors.
78	A Subcommittee member asked if there has been significant research on lower levels of exposure over long periods of time.	The government has for many years supported studies of low-level radiation exposure (e.g., reactor leaks). Even so, there are no data to show increased thyroid cancers in adults, but in very young children (under the age of 1), there may be some effect. The studies show that the effect is usually greater from an amount of radiation delivered as a single exposure rather than several smaller exposures.
79	A community member suggested comparing the data for thyroid cancer at ORR to those for the Hanford site.	The final report from the Hanford Thyroid Disease Study stated that "there was no evidence of a statistically significant association between estimated thyroid radiation dose from Hanford and the cumulative incidence of any of the 14 primary outcomes. There was also no evidence of any statistically significant dose-response relationship for any of the alternative definitions of outcome." Furthermore, the estimated amounts of iodines released from Hanford are 10 times more than the amount thought to have been released from X-10. For these reasons, ATSDR does not believe a comparison would be valid.
Diagnoses and treatment of thyroid disease		
Diagnosis of thyroid disease		
80	RaLa did expose people to iodine, and there probably are health effects. People still have to be advised to go to their doctors and be checked for thyroid cancer.	ATSDR feels that general medical evaluations are a component of good health practices. A physician should examine the thyroid for nodules as part of a general physical exam.

Community concerns from the Oak Ridge Reservation community health concerns database

	Actual comment/issue	*ATSDR's response*
81	Suppose you were born in 1980 and lived just across river from ORNL. You were absolutely unaffected by RaLa, but you may have been affected by the later release. You decide to send them a postcard to say go see your doctor. You may have gotten a level that makes you a little more likely to have trouble than the average. That would be the typical response. So if you were trying to decide whom to send postcards to, you would send to that individual.	According to information in the Task 1 report, "later" releases occurred in the late 1960s. Releases during this time frame would not have affected individuals born after 1980s (see page 4-20 of the Task 1 report). ATSDR supports annual physical examinations by your family physician.
82	A community member asked if the TSH test is supposed to show if something is wrong with the thyroid.	A TSH test will not show if something is wrong with the nodule, it will not show that there is a cancer. The patient can have thyroid cancer and a normal TSH. Thyroid cancer occurs most of the time in people who have normal thyroid function. Well over 90% of patients who have thyroid cancer have normal thyroid function until they are operated on, and the thyroid is removed.
83	A community member asked if a lack of nodules means the thyroid is o.k.	No, a lack of nodules does not indicate that the thyroid is disease free.
84	A community member also asked whether, because of the frequency of thyroid nodules, examining for them was part of a general physical exam.	Examining thyroid nodules is part of a general physical exam.
85	A Subcommittee member asked if the tests are generally covered by insurance.	Screening for TSH could possibly be covered, as the test is easily justified for people over age 60.
86	A Subcommittee member stated, as a person who had had a false positive result and the surgery, that having a surgery and living for any length of time with the terror that one might have cancer is not a trivial thing; it is really a life-altering experience.	ATSDR agrees. The issue of false positives as well as the risk from fine-needle biopsy of the thyroid has been addressed by the Institute of Medicine. They state that a fine-needle biopsy may yield indeterminate or unsatisfactory results probably 20% to 30% or more of the time.
Treatment of Thyroid Diseases		
87	A community member reported that pharmacists have said to her that synthroid medication is distributed from their pharmacies by the truckload each month.	ATSDR is not aware of the number of synthetic thyroid compounds distributed in the area. However, an Internet search indicated that the medication to which this comment refers was the third most commonly prescribed in the country during 2003, with 47.2 million prescriptions written.
88	A Subcommittee member asked if immunosuppressants are used to treat underactive thyroid.	Large amounts of Prednisone could be used to treat an underactive thyroid, but that bad side effects outweigh the benefits.